

## FULBRIGHT & JAWORSKI L.L.P.

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July 21, 2004

CERTIFICATE OF MAILING 37 C.F.R 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Flox 1450, Alexandria, VA 22313-1450, on the date below:

July 21, 2004

Date

Steven Highlander

MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

RE:

U.S. Patent Application No. 10/801,985 entitled "INHIBITION OF HISTONE"

DEACETYLASE AS A TREATMENT FOR CARDIAC HYPERTROPHY" – Carlin Long et

al.

Our reference: MYOG:034USC1 Client reference: UTSD:794US

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/MYOG:034USC1.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Steven L. Highlander Reg. No. 37,642

SLH/kmv

Encl.: as noted

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Carlin Long et al.

Serial No.: 10/801,985

Filed: March 16, 2004

For: INHIBITION OF HISTONE

DEACETYLASE AS A TREATMENT FOR CARDIAC HYPERTROPHY

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: MYOG:034USC1

CERTIFICATE OF MAILING 37 C.F.R 1.8

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July 21, 2004

Date

Steven Highlander

## **INFORMATION DISCLOSURE STATEMENT**

#### MS AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first

Official Action reflecting an examination on the merits, and hence is believed to be timely filed

in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the

filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R.

§§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the

Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit

Account No.: 50-1212/MYOG:034USC1.

This application is a continuation application of Serial No. 10/256,221, filed September

26, 2002 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with

Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been

previously cited by or submitted to the Patent and Trademark Office in prior application Serial

No. 10/256,221.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

Steven L. Highlander

Reg. No. 37,642

Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, Texas 78701 (512) 474-5201

Date:

July 21, 2004

Form PTO-1449 (modified)

JUL 2 8 2004

List of Patents and Publications for Applicant

MYOG:034USC1

Atty. Docket No.

Serial No. 10/801,985

Applicant

Carlin Long et al.

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date: March 16, 2004 Group: Unknown

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## **U.S. Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	Al	US 2002/0103192	8/1/02	Curtin et al.	514	227.8	3/14/01
	. A2	US 2002/0061860	5/23/02	Li et al.	514	44	8/6/01
	A3	US 2002/0065282	5/30/02	Georges et al.	514	238.2	12/4/01

## **Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
•	B1	EP 1170008	1/9/02	Europe			
	B2	EP 1174438	1/23/02	Europe			
	В3	JP 2001/348340	12/18/01	Japan			Abstract
	B4	WO 00/23112	4/27/00	PCT			
	B5	WO 00/71703	11/30/00	PCT			
	В6	WO 01/14581	3/1/01	PCT			
	В7	WO 01/16106	3/8/01	PCT			
	В8	WO 01/18045	3/15/01	PCT			
	В9	WO 01/38322	5/31/01	PCT			
	B10	WO 01/42437	6/14/01	PCT			
	B11	WO 01/70675	9/27/01	PCT			
	B12	WO 02/051842	7/4/02	PCT			
	B13	WO 02/26696	4/4/02	PCT			
	B14	WO 02/26703	4/4/02	PCT			
	B15	WO 02/30879	4/18/02	PCT			
	B16	WO 02/46129	6/13/02	PCT			
	B17	WO 02/46144	6/13/02	PCT			<del></del>

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**EXAMINER:** 

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Form PTO-1449 (modified)	··· -	Atty. Docket No.  MYOG:034USC1  Applicant  Carlin Long et al.		
List of Patents and Publications for	Applicant's			
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# **Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B18	WO 02/50285	6/27/02	PCT			
	B19	WO 01/17514	3/15/01	PCT			

# Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation					
	C1	Bates et al., "A phase I study of FR901228(Depsipeptide), a histone deacetylase inhibitor," American Society of Clinical Oncology Meeting 1999 Abstract, Abstract # 693, 1999, printed from www.medespace.com/cancero/doc/asco/1999/nouvdro/m_693.htm, May 7, 2001.					
	C2	Butler et al., "Inhibition of transformed cell growth and induction of cellular differentiation by pyroxamide, an inhibitor of histone deacetylase," Clin. Cancer Res., 7:962-970, 2001.					
	C3	Butler et al., "Suberoylanilide hydroxamic acid, an inhibitor of histone deacetylase, suppresses the growth of prostate cancer cells in vitro and in vivo," Cancer Res., 60:5165-5170, 2000.					
-	C4	Coffey et al., "The histone deacetylase inhibitor, CBHA, inhibits growth of human neuroblastoma xenografts in vivo, alone and synergistically with all-trans retinoic acid," Cancer Res., 61:3591-3594, 2001.					
	C5	Furumai et al., "FK228 (Depsipeptide) as a natural prodrug that inhibits class I histone deacetylases," Cancer Res., 62:4916-4921, 2002.					
	C6	Gottlicher et al., "Valproic acid defines a novel class of HDAC inhibitors inducing differentiation of transformed cells," EMBO J., 20:6969-6978, 2001.					
	C7	Han et al., "Apicidin, a histone deacetylase inhibitor, inhibits proliferation of tumor cells via induction of p21 WAF1/Cip1 and gelsolin," Cancer Research, 60:6068-6074, 2000.					
	C8	Haq, "Glycogen synthase kinase-3 $\beta$ is a negative regulator of cardiomyocyte hypertrophy," <i>J. Cell Biology</i> , 151:117-129, 2000.					
	C9	Hinnebusch et al., "The effects of short-chain fatty acids on human colon cancer cell phenotype are associated with histone hyperacetylation," J. Nutr., 132:1012-1017, 2002.					
	C10	Hoffmann et al., "Fluorescence-labeled octapeptides as substrates for histone deacetylase," Bioconjugate Chem., 12:51-55, 2001.					

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EXAMINER: DATE CONSIDERED:

Form PTO-1449 (modified)	<u>.</u>	Atty. Docket No.         Serial No.           MYOG:034USC1         10/801,985		
List of Patents and Publications for	Applicant's	Applicant Carlin Long <i>et al.</i>		
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	C11	Itazaki et al., "Isolation and structural elucidation of new cyclotetrapeptides, trapoxins A and B having detransformation activities as antitumor agents," J Antibiot (Tokyo), 43(12):1524-1532, 1990.					
	C12	Jung et al., "Amide analogues of trichostatin A as inhibitors of histone deacetylase and inducers of terminal cell differentiation," J. Med. Chem., 42:4669-4679, 1999.					
	C13	Jung et al., "Analogues of trichostatin A and trapoxin B as histone deacetylase inhibitors," Bioorganic & Medicinal Chemistry Letters, 7:1655-1658, 1997.					
	C14	Jung et al., "Structure-activity data on inhibitors of histone deacetylase-in vivo enzyme inhibition of differentiation and inhibition of proliferation in leukemic cells," Clin. Cancer Res., Suppl. 6: Abstract #336, 2000.					
	C15	Jung, "Inhibitors of histone deacetylase as new anticancer agents," Curr. Med. Chem., 8:1505-1511, 2001.					
	C16	Katoh et al., "MEF2B is a component of a smooth muscle-specific complex that binds an A/T-rich element important for smooth muscle myosin heavy chain gene expression," J. Biol. Chem., 273:1511-1518, 1998.					
	C17	Kim et al., "Oxamflatin is a novel antitumor compound that inhibits mammalian histone deacetylase," Oncogene, 18:2461-2470, 1999.					
	C18	Kitazono et al., "Low concentrations of the histone deacetylase inhibitor, depsipeptide (FR901228), increase expression of the Na <sup>+</sup> /I <sup>-</sup> symporter and iodine accumulation in poorly differentiated thyroid carcinoma cells," J. Clinical Endoc. Metabol., 86(7):3430-3435, 2001.					
	C19	Komastsu et al., "Cyclic hydroxamic-acid-containing peptide 31, a potent synthetic histone deacetylase inhibitor with antitumor activity," Cancer Res., 61:4459-4466, 2001.					
	C20	Kramer et al., "Histone deacetylase as a therapeutic target," Trends in Endoc. Metabolism, 12(7):294-300, 2001.					
	C21	Lu et al., "Signal-dependent activation of the MEF2 transcription factor by dissociation from histone deacetylases," Proc. Natl Acad. Sci. USA, 97:4070-4075, 2000.					
	C22	Mai et al., "Binding mode analysis of 3-(4-benzoyl-1-methyl-1H-2-pyrrolyl)-N-hydroxyy-2-propenamide: a new synthetic histone deacetylase inhibitor inducing histone hyperacetylation, growth inhibition, and terminal cell differentiation," J. Med. Chem., 45:1778-1784, 2002.					

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	C23	Marks et al., "Histone deacetylase inhibitors: inducers of differentiation or apoptosis of transformed cells," J. Natl. Cancer Inst., 92(15):1210-1216, 2000.
	C24	Marks et al., "Inhibitors of histone deacetylase are potentially effective anticancer agents," Clin. Cancer Res., 7:759-760, 2001.
	C25	Massa et al., "3-(4-Aroyl-1H-pyrrol-2-yl)-N-hydroxy-2-propenamides, a new class of synthetic histone deacetylase inhibitors," J. Med. Chem., 44:2069-2072, 2001.
	C26	Nicol et al., "Activated MEK5 induces serial assembly of sarcomeres and eccentric cardiac hypertrophy," <i>The EMBO J.</i> , 20(11):2757-2767, 2001.
	C27	Patrone et al., "Up regulation of the RET gene expression by histone deacetylase inhibitor sodium butyrate: hints to the gene physiologic regulation and applications for mutations screening," 50 <sup>th</sup> Annual Meeting of the American Society of Human Genetics, Abstracts, Program Number 1047, 2000.
	C28	Salminen et al., "Neuronal apoptosis induced by histone deacetylase inhibitors," Brain Res. Mol. Brain Res., 61:203-206, 1998.
	C29	Saunders et al., "Histone deacetylase inhibitors as potential anti-skin cancer agents," Cancer Res., 59-399-409, 1999.
	C30	Skaletz-Rorowski <i>et al.</i> , "The histone deacetylase inhibitors, trichostatin A and the new synthetic inhibitor M232, suprress the proliferation of corornary smooth muscle cells," <i>Eur. Heart J.</i> , Abstract Suppl., 21:272, Abstract #P1551, August/September 2000.
	C31	Su et al., "A novel histone deacetylase inhibitor identified by high-throughput transcriptional screening of a compound library," Cancer Res., 60:3137-3142, 2000.
	C32	Takahashi et al., "Selective inhibition of IL-2 gene expression by trichostatin A, a potent inhibitor of mammalian histone deacetylase," Antibiotics, 49:453-457, 1996.
	C33	Taunton et al., "A mammalian histone deacetylase related to the yeast transcriptional regulator Rpd3p," Science, 272:408-411, 1996.
	C34	Ueda et al., "FR901228, a novel antitumor bicyclic depsipeptide produced by Chromobacterium violaceum No. 968. I. Taxonomy, fermentation, isolation, physico-chemical and biological properties, and antitumor activity," J Antibiot (Tokyo), 47(3):301-310, 1994.

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	C35	Vigushin et al., "Histone deacetylase inhibitors in cancer treatment," Anticancer Drugs, 13:1-13, 2002.		
	C36	Vigushin et al., "Trichostatin A is a histone deacetylase inhibitor with potent antitumor activity against breast cancer in vivo," Cancer Res., 5(Suppl), Abstract #239, 1999.		
	C37	Vigushin et al., "Trichostatin A is a histone deacetylase inhibitor with potent antitumor activity against breast cancer in vivo," Clinical Cancer Res., 7:971-976, 2001.		
	C38	Yamano et al., "Amplification of transgene expression in vitro and in vivo using a novel inhibitor of histone deacetylase," 3 <sup>rd</sup> Annual Meeting of the American Society of Gene Therapy, Program Number 10, 2000.		
	C39	Yamano et al., "Amplification of transgene expression in vitro and in vivo using a novel inhibitor of histone deacetylase," Mol. Ther., Amer. Society of Gene Ther., 1(5):S20, Abstract #10, 2000.		
	C40	Yamano et al., "Construction and function of a recombinant adeno-associated virus encoding human interleukin-10," Mol. Ther., Amer. Society of Gene Ther., 1(5):S276, Abstract #764, 2000.		

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